

# Policy and Procedures for Creating a Limited Data Set

45 CFR 164.514(e)

**PURPOSE:** To establish a policy and procedures for creating a limited data set for the use or disclosure of protected health information (PHI) only for the purposes of research, public health, or health care operations.

**POLICY:** For purposes of research, public health, or health care operations, IHS may disclose information that is not fully de-identified if it creates a limited data set that complies with the terms of the Health Insurance Portability & Accountability Act (HIPAA) regulations, 45 CFR 164.514(e), and this Policy. Any disclosure by IHS must be made pursuant to a data use agreement with the recipient of the limited data set and must comply with the terms of this policy. All such disclosures must be made in accordance with the Policy and Procedure for Limiting the Use or Disclosure of Protected Health Information to the Minimum Necessary.

## DEFINITIONS:

Protected Health Information is health information that identifies a patient, or to which there is a reasonable basis to believe that the information can be used to identify the patient (for example, information contained in a primary health record or a third party billing claim record), excluding education records covered by the Family Educational Rights and Privacy Act, health records of students who are 18 years of age and older, and DHHS employment records.

Limited Data Set is PHI that excludes specified identifiers (such as name, provider name, chart number, social security number, etc.), but that can still potentially be linked to a particular patient because it contains dates (including birth date, admission date, discharge date, and date of death) and/or information about the patient's city, State or nine-digit zip code.

**PROCEDURE:** The following procedures shall be used to create a limited data set, which may be created only for the purposes of research, public health, or health care operations:

1. A limited data set is PHI that excludes the following direct identifiers of the patient or relatives, employers, or household members of the patient:
  - a. Names;
  - b. Postal address (may retain city, State, and nine-digit zip code);
  - c. Telephone numbers;
  - d. Fax numbers;
  - e. Electronic mail addresses;
  - f. Social security numbers;
  - g. Medical record numbers;
  - h. Health plan beneficiary numbers;
  - i. Account numbers;
  - j. Certificate/license numbers;
  - k. Vehicle identifiers and serial numbers, including license plate numbers;
  - l. Device identifiers and serial numbers;
  - m. Web Universal Resource Locators (URLs);
  - n. Internet Protocol (IP) address numbers;
  - o. Biometric identifiers, including finger and voice prints; and

- p. Full face photographic images and any comparable images.
2. A limited data set may contain:
    - a. Dates of admission and discharge, as well as dates of birth and death; and
    - b. Nine-digit zip codes, city, and State information.
  3. In order to create a limited data set, IHS may use PHI, or disclose PHI pursuant to a contract or other arrangement with a business associate for such purpose, whether or not the limited data set is to be used by IHS.
  4. A limited data set recipient must agree, in writing, to use or disclose the information only for the purposes of research, public health, or health care operations. A written data use agreement between IHS and the limited data set recipient must also:
    - a. Establish the permitted uses and disclosures of the information.
    - b. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in any manner that IHS could not;
    - c. Establish who is permitted to use or receive the limited data set; and
    - d. Provide that the limited data set recipient will:
      - i. Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
      - ii. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
      - iii. Report to the IHS (individual to be named in the agreement) any improper use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
      - iv. Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
      - v. Not identify the information or contact the patients.
    - e. If IHS becomes aware of a pattern of activity or practice of the recipient of the limited data set that constitutes a material breach or violation of the data use agreement, IHS must take reasonable steps to cure the breach or end the violation, as applicable. If such steps are unsuccessful, the IHS must:
      - i. Discontinue disclosure of PHI to the recipient; and
      - ii. Report the problem to the Secretary.
  5. IHS must comply with the terms of any limited data set agreement under which it receives information.
  6. Specific questions regarding the implementation of this policy should be directed to the SUD/CEO or designee.